REMARKS

This amendment is filed concurrently with a Request for Continued Examination.

Claim 2 has been amended to more clearly define the claimed invention. Support for the present amendment can be found in the description as originally filed on page 4, penultimate paragraph. Claims 2 and 6-8 are presently pending.

Rejections under 35 USC 112, First Paragraph

The Examiner rejected claims 2 and 6-8 under 35 USC 112, first paragraph as failing to comply with the enablement requirement. The Examiner stated that the claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner further rejected claims 2 and 6-8 under 35 USC 112, first paragraph as failing to comply with the written description requirement. The Examiner stated that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time of the application as filed, had possession of the claimed invention.

The Examiner stated that the application only provides a vague description of extracting grape skins. The Examiner stated that there is absolutely no description of the cabbage extraction and therefore there is no enabling description of how to make the cabbage extract.

Applicant respectfully disagrees. The description discloses a method for preparing grape skin extracts at page 3 of the description and that page 4, 1st paragraph of the description states that "[t]he experiments were repeated using cabbage extract". The person skilled in the art would readily understand that cabbage extracts of the present invention can be prepared using the same extraction methods as for grape skins. The disclosed methods for extracting grape skins were well known in the art as of the filing date as evidenced by enclosed excerpts taken from the Joint FAO/WHO Expert Committees on Food Additives Combined Compendium of Food Additive Specifications (JEFCFA, first referenced in 1984) and the Institute of Medicine (US) Committee on Food Chemicals Codex (2003). Both these reference volumes cite the same extraction method as disclosed in the present application. Accordingly, the skilled technician having regard to the general state of the art would readily be able to prepare grape skin extracts in accordance with these known methods and would also be able to apply the same extraction method to cabbage without any undue experimentation.

The Examiner stated that the application only provides enablement for a cabbage extract concentration of 27.5% only.

Claim 2 has been amended to recite to define the concentration of the pH indicated as being present in a concentration of about 27.5% by weight of the concentration.

In view of the present claim amendments and the preceding reasons, it is respectfully submitted that the claims are fully enabled and described in the specification.

Rejections under 35 USC 112

The Examiner rejected claims 2 and 6-8 under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The Examiner stated that there is no description of how the indicator is extracted and that it is not clear what "a concentration of about 10 to about 27.5%" means within the concentrate.

As discussed above, the person skilled in the art having regard to the general state of the art would be enabled to prepare the recited cabbage extract using the same methodology as for the extraction of grape skins. The person skilled in the art would readily understand that the cabbage extract can be prepared in the same manner and is added to the claimed concentrate in an amount such that the cabbage extract makes up 27.5% by weight of the concentrate. For these reasons, it is respectfully submitted that the claims are not indefinite. Reconsideration and withdrawal of the Examiner's objection is respectfully requested.

Rejection under USC 103(a)

The Examiner rejected claims 2 and 6-8 under 35 USC 103(a) as being unpatentable over Fisher in view of Freadman.

As previously submitted, Applicant submits that the invention claimed in the amended claims lies not in the discovery that red cabbage extract can be used as a pH indicator, Applicant admits that this was known on the relevant date for this application. In practice however, the skilled artisan also knows that it is very difficult to effectively use red cabbage extract as a pH indicator due to the very faint color change of the red cabbage extract required to show a deviation from the required pH range of 4 to 6. As result, the color change was previously so difficult to detect that for practical purposes the skilled artisan was unable to use red cabbage as a pH indicator for the purposes of the present invention. Through much time and labour, Applicant has been able to

determine that very large volumes of red cabbage extract are required in order to obtain a visually detectable color change that shows a deviation of from the required pH range of 4 to 6. Applicant has discovered that a visually detectable color change can be achieved where the red cabbage extract is present in a concentration of about 27.5% by weight of the concentrate.

Fisher fails to teach a pH indicator obtained from any type of plant source, let alone cabbage. Freadman discloses that indicators suitable for the disclosed method for detecting bacterial growth may also include natural indicators in the form of compounds derived from plants such as beets or cabbage. However, Freadman is absolutely silent as to the optimal concentration of such natural indicators either for the disclosed method or any other method. Thus, the Applicant respectfully submits that the cited references neither alone nor in combination teach nor suggest the amount of red cabbage extract that is required to achieve an effective visually detectable color change. It is therefore respectfully submitted that the amended claims patentably distinguish over the cited references.

Favourable reconsideration and allowance of this application are respectfully requested.

A Petition for an Extension of Time requesting an extension of three months for filing the subject response is enclosed. The Commissioner is authorized to charge any deficiency or credit any overpayment in the fees for same to our Deposit Account No. 500663.

Executed at Toronto, Ontario, Canada, on December 7, 2009.

MARTIN DAVID BLOOMBERG, ET AL.

By: 

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Customer Number: 38735

MLW:iw
Att. Petition for Extension of Time
Excerpts re Grape Skin Extract

(c) *Uses and restrictions.* Grape color extract may be safely used for the coloring of nonbeverage food, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches are exempt from the certification requirements of section 721(c) of the Act.

[46 FR 47532, Sept. 29, 1981]

§ 73.170 Grape skin extract (enocianina).

(a) *Identity.* (1) The color additive grape skin extract (enocianina) is a purplish-red liquid prepared by the aqueous extraction (steeping) of the fresh deseeded marc remaining after grapes have been pressed to produce grape juice or wine. It contains the common components of grape juice; namely, anthocyanins, tartaric acid, tannins, sugars, minerals, etc., but not in the same proportions as found in grape juice. During the steeping process, sulphur dioxide is added and most of the extracted sugars are fermented to alcohol. The extract is concentrated by vacuum evaporation, during which practically all of the alcohol is removed. A small amount of sulphur dioxide may be present.

(2) Color additive mixtures for food use made with grape skin extract (enocianina) may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Grape skin extract (enocianina) shall conform to the following specifications:

Pesticide residues, not more than permitted in or on grapes by regulations promulgated under section 408 of the Federal Food, Drug, and Cosmetic Act.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

(c) *Uses and restrictions.* Grape skin extract (enocianina) may be safely used for the coloring of still and carbonated drinks and ades, beverage bases, and alcoholic beverages subject to the following restrictions:

(1) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless artificial color is authorized by such standards.

(2) Its use in alcoholic beverages shall be in accordance with the provisions of parts 4 and 5, title 27 CFR.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. The common or usual name of the color additive is "grape skin extract" followed, if desired, by "(enocianina)".

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.185 Haematococcus algae meal.

(a) *Identity.* (1) The color additive haematococcus algae meal consists of the comminuted and dried cells of the alga *Haematococcus pluvialis.*

(2) Haematococcus algae meal may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with haematococcus algae meal may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Haematococcus algae meal shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Physical state, solid.

Lead, not more than 5 parts per million.

Arsenic, not more than 2 parts per million.

Mercury, not more than 1 part per million.

Heavy metals (as Pb), not more than 10 parts per million.
Astaxanthin, not less than 1.5 percent.

(c) *Uses and restrictions.* Haematococcus algae meal may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin in finished feed, from haematococcus algae meal when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing haematococcus algae meal shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[65 FR 41584, July 6, 2000]

§ 73.200 Synthetic iron oxide.

(a) *Identity.* (1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(2) Color additive mixtures for food use made with synthetic iron oxide may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* (1) Synthetic iron oxide for human food use shall conform to the following specifications:

Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Mercury (as Hg) , not more than 1 part per million.

(2) Synthetic iron oxide for dog and cat food use shall conform to the following specifications:

Arsenic (as As), not more than 5 parts per million.
Lead (as Pb), not more than 20 parts per million.
Mercury (as Hg), not more than 3 parts per million.

(c) *Uses and restrictions.* (1) Synthetic iron oxide may be safely used for the coloring of sausage casings intended for human consumption in an amount not exceeding 0.10 percent by weight of the finished food.

(2) Synthetic iron oxide may be safely used for the coloring of dog and cat foods in an amount not exceeding 0.25 percent by weight of the finished food.

(d) *Labeling requirements.* The label of the color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 59 FR 10578, Mar. 7, 1994]

§ 73.250 Fruit juice.

(a) *Identity.* (1) The color additive fruit juice is prepared either by expressing the juice from mature varieties of fresh, edible fruits, or by the water infusion of the dried fruit. The color additive may be concentrated or dried. The definition of fruit juice in this paragraph is for the purpose of identity as a color additive only and shall not be construed as a standard of identity under section 401 of the act.

GRAPE SKIN EXTRACT

Prepared at the 28th JECFA (1984), published in FNP 31/1 (1984) and in FNP 52 (1992). Metals and arsenic specifications revised at the 59th JECFA (2002). An ADI of 0-2.5 mg/kg bw was established at the 26th JECFA (1982)

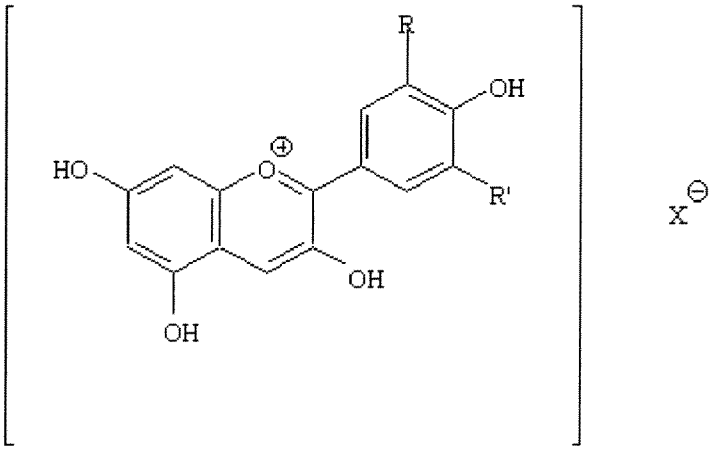
SYNONYMS Enociania, Eno; INS No. 163(ii)

DEFINITION Obtained by aqueous extraction of grape skin or marc after the juice has been expressed from it; contains the common components of grape juice, namely: anthocyanine, tartaric acid, tannins, sugars, minerals, etc., but not in the same proportions as found in grape juice. During the extraction process, sulphur dioxide is added and most of the extracted sugars are fermented to alcohol; the extract is concentrated by vacuum evaporation during which practically all the alcohol is removed; a small amount of sulphur dioxide may be present.

Chemical names The principal colouring matters are anthocyanins, glucosides of anthocyanidins (2-phenylbenzopyrylium salts) such as peonidin, malvidin, delphinidin, and petunidin.

Chemical formula
Peonidin: $C_{16}H_{13}O_6X$
Malvidin: $C_{17}H_{15}O_7X$
Delphinidin: $C_{15}H_{11}O_7X$
Petunidin: $C_{16}H_{13}O_7X$
X: acid moiety

Structural formula



Peonidin: R = OCH_3; R' = H
Malvidin: R, R' = OCH_3
Delphinidin: R, R' = OH
Petunidin: R = OCH_3; R' = OH
X^-: acid moiety

Assay The colour intensity is not less than declared

DESCRIPTION Purplish-red liquid, lump, powder or paste, having a slight characteristic odour

FUNCTIONAL USES Colour

CHARACTERISTICS

IDENTIFICATION

Solubility (Vol. 4)	Soluble in water
Spectrophotometry (Vol. 4)	At pH 3 the absorbance maximum is about 525 nm
Colour reaction	Add 0.1 g of the sample to 50 ml of water and shake thoroughly. Filter if necessary. The solution shows red to purplish-red colour and it turns to blue or dark green on the addition of sodium hydroxide TS.

PURITY

Sulfur dioxide	Not more than 0.005% per 1 colour value Distil 1 g of the sample with 100 ml of water and 25 ml of phosphoric acid solution (2 in 7) in a distilling flask with the Wagner tube (Figure 1). In an absorption flask, place 25 ml of lead acetate solution (1 in 50) previously prepared. Insert the lower end of condenser into lead acetate solution in the absorption flask. Distil until the liquid in the absorption flask reaches about 100 ml and rinse the end of the condenser with a little amount of water. To the distilled solution add 5 ml of hydrochloric acid and 1 ml of starch TS, and titrate with 0.01 N iodine. Each ml of 0.01 N iodine is equivalent to 0.3203 mg of SO_2.

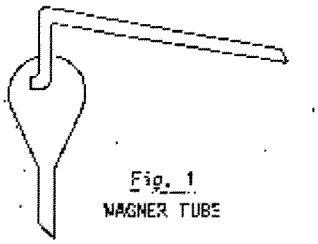


Fig. 1
WAGNER TUBE

Basic colouring matters	Add 1 g of the sample to 100 ml sodium hydroxide solution (1 in 100) and shake well. Take 30 ml of this solution and extract with 15 ml of ether. Extract this ether extract twice with each 5 ml of dilute acetic acid TS. The acetic acid extract is colourless.
Other acidic colouring matters	Add 1 ml of ammonia TS and 10 ml of water to 1 g of the sample and following the directions *Chromatography* place 0.002 ml of the solution on the chromatographic sheet and dry it. Use a mixture of pyridine and ammonia TS (2:1 by volume) as developing solvent and stop the development when the solvent front reaches about 15 cm height from the point where the sample solution was placed. No spot is observed at the solvent front after drying under daylight. If any spot is observed, it should be decolourized when sprayed with a solution of stannous chloride in hydrochloric acid (2 in 5).

Lead (Vol. 4)

Not more than 2 mg/kg
Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4, "Instrumental Methods."

METHOD OF ASSAY

In the absence of an assay method, a measurement of colour intensity by the following method may be used.

Prepare approximately 200 ml of pH 3.0 citric acid - dibasic sodium phosphate buffer solution: Mix 159 volumes of 2.1% citric acid solution and 41 volumes of 0.16% dibasic sodium phosphate solution, and adjust the pH to 3.0, using the citric acid solution or dibasic sodium phosphate solution. Weigh accurately an adequate amount of the sample so that the measured absorbance is between 0.2 and 0.7, and add pH 3.0 citric acid - dibasic sodium phosphate buffer solution to make up a 100-ml solution. Measure the absorbance A of this solution in a 1 cm cell at the wavelength of maximum absorption around 525 nm, using pH 3.0 citric acid - dibasic sodium phosphate buffer solution as the blank.

$$Colour\ value = \frac{A \times 10}{weight\ of\ sample\ (g)}$$

Food chemicals codex By Institute of Medicine (U.S.). Committee on Food Chemicals Codex

Loss on Drying Determine as directed under *Loss on Drying*, Appendix IIC, drying a sample at 105° for 5 h.
Residue on Ignition Determine as directed under *Residue on Ignition*, Appendix IIC, heating a 2-g sample

Packaging and Storage Store in well-closed containers.

Grapefruit Oil, Coldpressed

Grapefruit Oil, Expressed, Oil of Shaddock

CAS [8016-20-4]

DESCRIPTION

Grapefruit Oil, Coldpressed, occurs as a yellow, sometimes red, liquid that often shows a flocculent separation of waxy material. It is the oil obtained by expression from the fresh peel of the grapefruit (*Citrus paradisi* Macfadyen; *Citrus x aurantium* L.) (Fam. Rutaceae). It is soluble in most fixed oils and in mineral oil, often with opalescence or cloudiness. It is slightly soluble in propylene glycol and insoluble in glycerin. It may contain a suitable antioxidant.

Function Flavouring agent

REQUIREMENTS

Identification The infrared absorption spectrum of the sample exhibits relative maxima at the same wavelengths as those of a typical spectrum as shown under *Infrared Spectra*, using the same test conditions as specified therein.
Angular Rotation Between +91° and +96°
Refractive Index Between 1.475 and 1.478 at 20°
Residue on Evaporation Between 5.0% and 10.0%
Specific Gravity Between 0.848 and 0.856

TESTS

Angular Rotation Determine as directed under *Optical Specific Rotation*, Appendix IIB, using a 100-mm tube.
Refractive Index Determine as directed under *Refractive Index*, Appendix IIB, using an Abbe or other refractometer of equal or greater accuracy.
Residue on Evaporation Determine as directed under *Residue on Evaporation*, Appendix VI, heating a sample for 5 h.
Specific Gravity Determine by any reliable method. See *General Provisions*.

Grape Skin Extract

Enocyanina

INS No.163(ii)

CAS [84929-27-1]

DESCRIPTION

Grape Skin Extract occurs as a red to purple powder or liquid concentrate. It is prepared by aqueous extraction of grape mass remaining from the pressing of grapes to obtain juice. Extraction is effected with water containing sulfur dioxide. During the steeping process, sulfur dioxide is added and the sugar content is reduced by fermentation. Further concentration removes most of the alcohol. The primary color components are anthocyanins such as the glucosides of malvidin, peonidin, petunidin, delphinidin, or cyanidin. Other components naturally present are sugars, tartrates, malates, tannins and minerals. The powder may contain an added carrier such as maltodextrin, modified starch, or gum. In acid solution, Grape Skin Extract is red, in neutral to alkaline solution, it is unstable and color is blue.

Function Color

REQUIREMENTS

Identification Transfer 1 g of sample and 1 g of potassium metabisulfite to a 100-mL volumetric flask, dissolve in about 80 mL of pH 3.0 *Citrate–Citric Acid Buffer*, see Assay below, and dilute to volume with the same buffer. The red color caused by anthocyanins is bleached.
Assay Not less than 90% of the color strength as represented by the vendor.
Arsenic Not more than 1 mg/kg
Lead Not more than 5 mg/kg

TESTS

Assay

pH 3.0 Citrate–Citric Acid Buffer Add, dropwise, 0.1 M sodium citrate to 0.1 M citric acid until a pH of 3.0 is reached as determined by a glass electrode.

Procedure Transfer about 0.2 g of sample, accurately weighed, to a 100-mL volumetric flask, dissolve it in about 25 mL of pH 3.0 *Citrate–Citric Acid Buffer*, and dilute to volume with the same buffer. Remove any undissolved material by filtration or centrifugation. Adjust the pH to 3.0, and determine the absorbance of the clarified solution at the maximum near 535 nm in a cell with a 1-cm pathlength. The